

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

SCIELE PHARMA, INC. <i>et al.</i> ,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. 09-037 (RBK) (JS)
	)	(CONSOLIDATED)
LUPIN LTD., <i>et al.</i> ,	)	
	)	REDACTED VERSION
Defendants.	)	
	)	

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**LUPIN'S REPLY BRIEF IN FURTHER SUPPORT OF ITS  
MOTION FOR A PROTECTIVE ORDER CONCERNING ITS  
HIGHLY SENSITIVE COMMERCIAL INFORMATION  
INVOLVING COMMERCIAL RELATIONSHIPS AND  
SETTLEMENT NEGOTIATIONS**

May 7, 2012

BAYARD P.A.

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OF COUNSEL

Douglass C. Hochstetler  
Kelley Drye & Warren LLP  
333 West Wacker Drive, 26th Floor  
Chicago, IL 60606  
(312) 258-2629  
dhochstetler@kelleydrye.com

Beth D. Jacob  
Kelley Drye & Warren LLP  
101 Park Avenue  
New York, NY 10178  
(212) 808-7624  
bjacob@kelleydrye.com

Karen A. Confoy  
Erica S. Helms  
Sterns & Weinroth  
50 W. State Street, Ste. 1400  
Trenton, NJ 08607

Richard D. Kirk (rk0922)  
Stephen Brauerman (sb4952)  
Vanessa R. Tiradentes (vt5398)  
222 Delaware Avenue, 9th Floor  
P.O. Box 25130  
Wilmington, DE 19899-5130  
(302) 655-5000  
rkirk@bayardlaw.com  
sbrauerman@bayardlaw.com  
vtiradentes@bayardlaw.com  
  
*Attorneys for Defendants  
Lupin Ltd. and Lupin Pharmaceuticals, Inc.*

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## **INTRODUCTION**

Plaintiff Sciele Pharma, Inc., n/k/a Shionogi, Inc. (“Shionogi”) is asking this Court to force Lupin Ltd. and Lupin Pharmaceuticals, Inc. (collectively “Lupin”) to produce highly sensitive commercial information to its direct competitors, which, if disclosed to and acted upon by its competitors, would seriously jeopardize Lupin’s ability to compete in the market. Shionogi relies upon a second declaration from Christopher P. Gerardi, dated May 1, 2012 (“Gerardi II”), but this declaration does not cure the defects of his initial declaration submitted on April 2, 2012. Shionogi makes only conclusory assertions regarding the relevance of Lupin’s highly sensitive information and information relating to the transfer of the ANDA, and fails to demonstrate necessity for the information. As Lupin’s expert, Ivan T. Hofmann, CPA/CFF, CLP explains in his second declaration (“Hofmann II”), these conclusory assertions ignore the realities of the prescription drug market and the information actually necessary and relevant to a damages calculation in a Hatch-Waxman case like this one. Additionally, Shionogi has not presented any evidence to dispute Lupin’s showing through its Senior Vice President of Sales & Marketing, that it would be – as found by this Court – “incredibly harmful” if its highly sensitive information is disclosed.<sup>1</sup> Indeed, Shionogi and Mr. Gerardi admit that the information is highly sensitive. Therefore, the harm to Lupin if its highly sensitive information is disclosed outweighs any benefit to Shionogi, and the Court should grant Lupin’s request for a protective order.

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<sup>1</sup> The declaration of Robert G. Hoffman, Senior Vice President of Sales & Marketing for Lupin Pharmaceuticals, Inc., dated October 20, 2011, is attached to the April 23, 2012 Declaration of Stephen Brauerman (“Brauerman (4/23/12)”) as Exhibit 3. It is referred to herein as “Hoffman Decl.”

## ARGUMENT

### **I. SHIONOGI SEEKS IRRELEVANT AND UNNECESSARY INFORMATION AND THE HARM TO LUPIN OUTWEIGHS ANY BENEFIT TO SHIONOGI.**

#### **A. Shionogi Has Not Met Its Burden**

Shionogi must show that the highly sensitive information it seeks “is sufficiently relevant and necessary to [its] case to outweigh the harm disclosure would cause” to Lupin. *In re Brand Name Prescription Drugs Antitrust Litig.*, 94 C 897, 1994 U.S. Dist. LEXIS 17278, at \*3 (N.D. Ill. Dec. 5, 1994) (holding that the plaintiffs failed to show that the defendant drug manufacturer’s cost/profit information for individual products is relevant and necessary); *accord Ikon Office Solutions, Inc. v. Konica Minolta Bus. Solutions*, No. 3:08-CV-539-RLV-DCK, 2009 U.S. Dist. LEXIS 116372, at \*14 (W.D.N.C. Nov. 25, 2009). An “obscure showing” that the information “*may* be relevant . . . is not sufficient to force disclosure” of Lupin’s highly sensitive information. *Brand Name Prescription Drugs*, 1994 U.S. Dist. LEXIS 17278, at \*8 (emphasis in original). Even if Shionogi shows that the “information sought could be used to prove damages,” it still must “establish the necessity of the information.” *Id.* at \*7. Shionogi has failed to satisfy this burden; its opposition brief, including Gerardi II, contains only conclusory assertions. *See Sony Corp. of Am. v. Soundview Corp. of Am.*, No. 3:00 CV 754 (JBA), 2001 WL 1772920, at \*4 (D. Conn. Oct. 23, 2001) (“conclusory allegations are not reasonably calculated to lead to the discovery of admissible evidence”).

#### **B. The Disclosure of Lupin’s Highly Sensitive Commercial Information Would Be “Incredibly Harmful”**

As an initial matter, Shionogi does not dispute that the information it seeks is highly sensitive. Indeed, Shionogi’s expert admits that “competition among branded and generic companies and competition between generic companies may result in ‘heightened commercial sensitivity’ of highly confidential information.” (Gerardi II at ¶ 10(c); *see also* Hofmann II at ¶

23.) Shionogi, instead, argues that Lupin failed to meet its burden of showing harm if the highly sensitive information is disclosed, but in doing so, Shionogi ignores the Declaration of Robert G. Hoffman, Lupin's Senior Vice President of Sales & Marketing. In support of this motion, Lupin re-submitted the Hoffman Declaration, which was previously submitted in opposition to Shionogi's attempt to obtain the highly sensitive information during the briefing on the motion for a preliminary injunction. Mr. Hoffman is responsible for all sales and marketing of Lupin's generic business in the U.S. (Hoffman Decl. at ¶ 3.) Mr. Hoffman gave concrete reasons why disclosure of Lupin's highly sensitive information would be harmful, including the following:



██████████<sup>2</sup>

Likewise, in Mr. Hofmann’s expert opinion: “Disclosure of this information to competitors is likely to cause Lupin harm across customers and product portfolios by allowing the competitor to undercut Lupin’s price on several products, not just its generic metformin hydrochloride extended release product.” (Hofmann II at ¶ 25; *see also* ¶¶ 21-24; Hofmann I at ¶¶ 28-30.) Moreover, this Court previously held it would be “incredibly harmful” if Lupin’s information fell into the hands of its competitors. (Brauerman (4/23/12), Ex. 1 at 18:1-5.)

Next, Shionogi argues that Lupin will not suffer harm because the highly sensitive information would be covered by the Protective Order, and Lupin relies on confidentiality agreements to protect the same information. Shionogi fails to acknowledge a few key distinctions between the Protective Order in this case and Lupin’s confidentiality agreements with its customers. First, the customers see only the confidential terms in agreements to which they are parties, *e.g.*, Wholesaler A would not know the terms of Wholesaler B’s contract. Shionogi and Andrx (Lupin’s brand and generic direct competitors), in contrast, seek information for all customers and other internal Lupin strategy documents. Information about all of Lupin’s customers, along with Lupin’s internal documents, would essentially allow a competitor to determine Lupin’s sales, marketing and pricing strategies and use the information to take business away from Lupin. (Hoffman Decl. at ¶¶ 8-11.) Second, Shionogi fails to point out the obvious difference between turning over highly sensitive information to direct competitors as compared to customers. Lupin’s competitors “have strong incentives to act on the information received to the detriment of Lupin.” (Hofmann II at ¶¶ 21-22.) “As courts have long

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<sup>2</sup> Based on the foregoing “specific examples and reasons” – completely ignored by Shionogi – Shionogi’s reliance on *AstraZeneca LP v. Breath Ltd.* is misplaced. *See* No. 08-1512, 2011 WL 1421800, at \*10-11 (D.N.J. Mar. 31, 2011) (AstraZeneca purportedly made only “conclusory statements” regarding harm and relied on Swedish Trade Secret Protection Act to argue that the documents are protected as trade secrets under Swedish law).

recognized, disclosure of sensitive business information to a competitor is more harmful than disclosure to a noncompetitor.” *Spartanburg Reg. Healthcare Sys. v. Hillenbrand Indus. Inc.*, 1:05-mc-107, 2005 U.S. Dist. LEXIS 30594, at \*10 (W.D. Mich. 2005) (denying competitor’s attempt to obtain information “detailing sensitive and confidential aspects of Steelcase’s business strategy”), *aff’d*, 2005 U.S. Dist. LEXIS 30590 (W.D. Mich. Oct. 12, 2005).

Furthermore, courts have recognized that protective orders do not offer a 100% guarantee to the producing party, and thus, balance the requesting party’s need for the information against the potential harm. *See, e.g., Stanley Works v. Newell Co.*, Case No. 92 C 20157, 1992 U.S. Dist. LEXIS 13817, at \*16 (N.D. Ill. Aug. 27, 1992) (“There is constant danger inherent in disclosure of confidential information pursuant to a protective order.”); *Wear-Guard Corp. v. Van Dyne-Crotty, Inc.*, No. 90-1948, 1990 U.S. Dist. LEXIS 17039, at \*10 (E.D. Pa. Dec. 13, 1990) (protective order “was never intended and could not be used to permit plaintiff’s unjustified access to irrelevant information having such a high degree of sensitivity”).<sup>3</sup> Indeed, this Court previously acknowledged the risk that the highly sensitive information can “escape the confines of that Protective Order.” (Brauerman (4/23/12), Ex. 1 at 18:3-5.) Moreover, “a protective order which limits to whom information may be disclosed does not eliminate the requirements of relevance and need for information.” *Micro Motion Inc. v. Kane Steel Co.*, 894 F.2d 1318, 1325 (Fed. Cir. 1990). As discussed below, Shionogi cannot meet these requirements.

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<sup>3</sup> In attempting to distinguish the cases cited by Lupin in its Opening Brief, Plaintiffs mischaracterize the facts and holdings therein. For example, in *Greater Rockford Energy & Technology Corp. v. Shell Oil Co.*, 138 F.R.D. 530 (C.D. Ill. 1991), the court found the likelihood of inappropriate disclosure minimal, but still denied the motion to compel because of the devastating effect if disclosure did occur and the protective order would not shield the information from experts whose “raison d’être is to assimilate information” and who would be unlikely to forget plaintiff’s confidential information. *Id.* at 537-38 (quoting *Litton Indus. v. Chesapeake & Ohio Ry.* 129 F.R.D. 528, 531 (E.D. Wisc. 1990)).

**C. Shionogi Has Not Demonstrated that the Information Is Relevant and Necessary and the Benefit to Shionogi Outweighs Harm To Lupin**

Shionogi's expert, Mr. Gerardi, asserts repeatedly that "while Mr. Hofmann may be of the opinion that many of the documents requested by Shionogi may be irrelevant and/or unnecessary to determine damages," he "may draw different conclusions." These conclusory assertions are meaningless and do not satisfy Shionogi's burden. *See Pioneer Hi-Bred Int'l Inc. v. Holden's Found. Seeds, Inc.*, 105 F.R.D. 76, 82 (N.D. Ind. 1985) (denying request for trade secret information because "general, conclusory assertions" that the information is relevant "are not sufficient"). For the most part, Mr. Gerardi does not explain *how* he (or any "independent expert") would use the information or *why* it is necessary that he review it.<sup>4</sup> Instead, Mr. Gerardi repeatedly states in conclusory fashion that any independent expert would want to review the information, but these statements are not reasons for why the information is relevant and necessary.

Based on the characteristics of the market for prescription drugs, damages analyses require different information as compared to other patent infringement cases even though many of the same legal principles from *Panduit* and *Georgia-Pacific* apply.<sup>5</sup> As Mr. Hofmann states, there is no "One Size Fits All" approach to damages discovery in patent infringement cases. (Hofmann II at ¶¶ 3-4.) For this reason, the cases and treatises cited by Shionogi, making general statements about damages discovery, are not instructive. (Hofmann II at ¶¶ 18-19.)<sup>6</sup>

<sup>4</sup> As explained by Mr. Hofmann, Mr. Gerardi's few attempts to provide examples of how the information may be used have no basis in fact, reflect a lack of understanding of the market, and/or are incoherent. (Hofmann II at ¶¶ 8-13, 16.)

<sup>5</sup> Contrary to the straw man created by Shionogi in its opposition (*see* Shionogi Opp. at 7-8), Lupin did not argue that different legal standards applied to the damages analysis in this Hatch-Waxman case, just that the discovery needed to be tailored to the specific market factors.

<sup>6</sup> In the cases cited by Shionogi, the courts pointed to the *Panduit* and *Georgia-Pacific* factors for a damages analysis, but did not consider whether the same type of information sought by Shionogi here is necessary for that analysis. *See Sanofi-Aventis Deutschland GmbH v. Glenmark*

Shionogi makes a failed attempt to provide an example of how Lupin's information may be relevant to demand, *i.e.*, cross-referencing a decline in sales of Fortamet<sup>®</sup> to one customer (*e.g.*, Walmart or CVS) with corresponding sales of Lupin's generic product to the same customer. (Shionogi Opp. at 10-11; Gerardi II at ¶ 3(i).) This purported example reflects a lack of understanding of the prescription drug market. (Hofmann II at ¶ 10.) As Mr. Hofmann explains, the demand for the product is driven by physician prescribing behavior. (Hofmann II at ¶ 8.) "Pharmacists are not permitted to substitute a different product for a prescribed brand or generic product other than a generic equivalent product without permission from the prescribing physician. The customers of the brand and generic pharmaceutical companies are typically intermediaries (*i.e.* distributors, wholesalers, or retailers)." (*Id.*) Thus, customer-specific information is not needed to determine the demand for Shionogi's product or for any other damages calculations. (Hofmann II at ¶¶ 12-20.) This example also ignores the sales of the other generic product now on the market sold by Shionogi's co-plaintiff, Andrx.

Shionogi argues that customer-specific information is also needed to determine whether Lupin expanded the market beyond the Fortamet<sup>®</sup> market pre-generic launch. But, as Mr. Hofmann explains, customer-specific information would not be instructive or necessary; rather, such an analysis would be performed by reviewing Shionogi's and Lupin's forecasts in conjunction with IMS data showing the "overall sales" of Fortamet<sup>®</sup> and generic metformin hydrochloride extended release product, and IMS data of the competing products, Glumetza<sup>®</sup> and Glucophage<sup>®</sup>, along with their generic equivalents. (Hofmann Reply Decl. at ¶¶ 11-12.) *See also Spartanburg*, 2005 U.S. Dist. LEXIS 30594, at \*13 (stating that availability of information

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*Pharmas. Inc.*, 821 F. Supp. 2d 681 (D.N.J. 2011) (finding that defendant generic company conceded that plaintiff would have made the sales based on the defendant's damages calculation); *In re Gabapentin Patent Litig.*, 2011 WL 1807448, at \*2-3 (D.N.J. May 12, 2011) (finding that off-label promotion is non-patented element); *Abbott Labs. v. Sandoz, Inc.*, 743 F. Supp. 2d 762, 784 (N.D. Ill. 2010) (considering the admissibility of the patentee's documents).

sought from alternate source “greatly diminishes” argument for need).

Customer-specific information also is not needed for alleged damages based on price erosion. Importantly, Shionogi has never claimed that it lowered its prices or that it offered discounts that had the effect of lowered prices. Nor is there any evidence in the record of price erosion. Certainly, Shionogi would be in the best position to know whether its own prices decreased. As Mr. Hofmann explains, “documents required to calculate price erosion damages would come from Shionogi, not Lupin.” (Hofmann II at ¶ 17.)

Shionogi also claims it needs Lupin’s highly sensitive information to show the secondary consideration of “commercial success.” Shionogi will be required to show that Fortamet<sup>®</sup> is commercially successful and that there is a “nexus” between the “commercial success” and the patented features of the product. *See King Pharms., Inc. v. Eon Labs, Inc.*, 616 F.3d 1267, 1281 (Fed. Cir. 2010). As Mr. Hofmann explains “[a] commercial success inquiry typically focuses on the performance of the branded product prior to generic competition” and the nexus inquiry examines “whether the alleged commercial success is due to the unique claims of the patent.” (Hofmann II at ¶ 43.) The information needed for these analyses are typically from the branded company’s records and third party data. (Hofmann II at ¶ 38.) *See, e.g., Pfizer Inc. v. Apotex Inc.*, 731 F. Supp. 2d 754, 759 (N.D. Ill. 2010) (commercial success analysis focused on Lipitor<sup>®</sup>’s “past commercial success”); *Daiichi Sankyo Co., Ltd. v. Mylan Pharms. Inc.*, 670 F. Supp. 2d 359, 384-87 (D.N.J. 2009) (examining branded product’s net sales, annual prescriptions, market share, and profitability). Moreover, in its business plans, Shionogi admits that, before there was a generic on the market, Fortamet<sup>®</sup> sales were declining and it decided to cease promotional activities. (Braerman (5/7/12), Exs. A-B.)<sup>7</sup>

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<sup>7</sup> The Gerardi Declaration does not provide support for Shionogi’s argument that it needs the information to examine “commercial success.”

Finally, the Court should reject Shionogi’s unfounded argument that Lupin is withholding documents because they would be “unhelpful” to Lupin. There is nothing in the record to suggest that Lupin or its counsel are doing anything other than zealously protecting its highly sensitive business information to safeguard its ability to compete in the market.

Shionogi has access to, or Lupin has agreed to produce, the information that would be relevant and necessary, including: (a) Shionogi's own information; (b) IMS data regarding the market for Fortamet<sup>®</sup> and its generic equivalents; (c) IMS data regarding the market for Glumetza<sup>®</sup> and Glucophage<sup>®</sup>, and their generic equivalents; and (d) information Lupin already agreed to produce, namely, total net sales and units sold of Lupin's product and Lupin's forecasts. (Hofmann II at ¶¶ 15-16, 46; Brauerman (5/7/12), Ex. C at Req. Nos. 43, 52-53.)<sup>8</sup> Considering Shionogi's failure to demonstrate necessity and relevance, "[g]iven the volume of material requested and its extremely sensitive nature, the potential harm to [the producing party] is significant and easily outweighs whatever need [the requesting party] may have for such material." *Spartanburg*, 2005 U.S. Dist. LEXIS 30594, at \*14.

A horizontal bar chart titled "U.S. should take action to address climate change" showing the percentage of respondents who believe the U.S. should take action to address climate change, broken down by age group. The y-axis lists age groups: 18-29, 30-49, 50-69, 70+, and Overall. The x-axis represents the percentage, ranging from 0 to 100. The bars are dark blue. The data is as follows:

Age Group	Percentage
18-29	88%
30-49	85%
50-69	82%
70+	78%
Overall	83%

<sup>8</sup> Contrary to Shionogi's unsupported claim, the relevance of Shionogi's documents for a damages analysis has no bearing on the relevance of Lupin's documents. (Hofmann II at ¶ 41.)

[illegible]

## CONCLUSION

For the foregoing reasons, Lupin respectfully requests this Court to issue a Protective Order precluding plaintiffs from obtaining Lupin’s highly sensitive commercial information.

<sup>9</sup> The cases relied upon by Shionogi are inapposite because they involve negotiations or settlements regarding a license to sell a patented product and the related royalty. An ANDA, by contrast, is not a license to sell a patented product. Also in both *Board of Trustees of Leland Stanford Junior University. v. Tyco International Ltd.*, 253 F.R.D. 521, 523 (C.D. Cal. 2008), and *In re MSTG, Inc.*, -- F.3d --, 2012 WL 1155736, at \*6 (Fed. Cir. 2012), the party was attempting to withhold documents regarding settlements or negotiations on which it was relying. In contrast, Lupin will not rely upon information that it will not produce.

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BAYARD P.A.

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OF COUNSEL

Douglass C. Hochstetler  
Kelley Drye & Warren LLP  
333 West Wacker Drive, 26th Floor  
Chicago, IL 60606  
(312) 258-2629  
dhochstetler@kelleydrye.com

Beth D. Jacob  
Kelley Drye & Warren LLP  
101 Park Avenue  
New York, NY 10178  
(212) 808-7624  
bjacob@kelleydrye.com

Karen A. Confoy  
Erica S. Helms  
Sterns & Weinroth  
50 W. State Street, Ste. 1400  
Trenton, NJ 08607

/s/ Stephen B. Brauerman  
Richard D. Kirk (rk0922)  
Stephen Brauerman (sb4952)  
Vanessa R. Tiradentes (vt5398)  
222 Delaware Avenue, 9th Floor  
P.O. Box 25130  
Wilmington, DE 19899-5130  
(302) 655-5000  
rkirk@bayardlaw.com  
sbrauerman@bayardlaw.com  
vtiradentes@bayardlaw.com

*Attorneys for Defendants  
Lupin Ltd. and Lupin Pharmaceuticals, Inc.*